

**Kinser, Robin D.**

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**From:** Kinser, Robin D.  
**Sent:** Tuesday, February 06, 2001 2:59 PM  
**To:** Oey, Jan  
**Cc:** Kinser, Robin D.  
**Subject:** RE: Phenotyping

Jan--I have edited for you consideration. If you like what I've suggested, please delete the text with strike-throughs, copy, paste and send! --Robin

Dear Jill,

These are our comments to the specific issues regarding Draft No.1 Research Protocol:

Independent laboratory for corroboration of malondialdehyde determination needs to be determined/information supplied.  
The independent laboratory has been identified and discussions have been initiated. This will be discussed further February 15.

Sputum sampling: needs to be determined if it will be done (and, if so, at what timepoints and using what method for collection/storage/shipping)

Yes, sputum sampling will be done at Enrollment, Week 3, and Week 6. Methods are to be discussed February 15.

CYP1A2 and NAT-2 phenotyping needs to have explanation of method of challenge

We will acquire the challenge method

~~The so-called "caffeine test" is to be maintained in the protocol. Robin: please check with Tony about the method and reference.~~

Methods and references needed for some analytes. Also pertains to Appendix B for the amounts of each sample needed for analytical procedures.

We need more specific questions here. It is our understanding that methods have been defined for all analytes. Sample amounts will have to come from Covance as methods are developed.

~~Since Covance is developing the methods, please refer to Keith Phillips and associates~~

**Robin Kinser**  
**804-274-5905**  
**Robin.D.Kinser@pmusa.com**

-----Original Message-----

**From:** Oey, Jan  
**Sent:** Tuesday, February 06, 2001 11:56 AM  
**To:** Kinser, Robin D.  
**Subject:** Phenotyping

Dear Robin,  
I have prepared this draft email for Jill, please check.  
Thanks, Jan

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Dear Jill,

These are our comments to the specific issues regarding Draft No.1 Research Protocol:

Independent laboratory for corroboration of malondialdehyde determination needs to be determined/information supplied.

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This issue is still pending and will be discussed February 15.

Sputum sampling: needs to be determined if it will be done (and, if so, at what timepoints and using what method for collection/storage/shipping)

Yes, sputum sampling will be done at Enrollment, Week 3, and Week 6. Methods are to be discussed February 15.

CYP1A2 and NAT-2 phenotyping needs to have explanation of method of challenge

The so-called "caffeine test" is to be maintained in the protocol. *Robin: please check with Tony about the method and reference.*

Methods and references needed for some analytes. Also pertains to Appendix B for the amounts of each sample needed for analytical procedures.

Since Covance is developing the methods, please refer to Keith Phillips and associates.